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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,528	06/23/2000	Jan Eirik Ellingsen	06275-199001	9997

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EXAMINER	
CULBERT, ROBERTS P	

ART UNIT	PAPER NUMBER
1763	

DATE MAILED: 08/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/602,528	ELLINGSEN ET AL.	
	Examiner	Art Unit	
	Roberts Culbert	1763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7,10,20,23,27,30,34,37,44,51 and 79-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7, 10, 20, 23, 27, 30, 34, 37, 44, 51 and 79-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/21/04 has been entered.

Response to Arguments

Applicant's arguments filed 6/21/04 have been fully considered but they are not persuasive.

Applicant has argued that nothing in JP 3146679 suggests that there is some improvement in implant adhesion at HF concentrations below 1%.

The argument is not persuasive because JP 3146679 does suggest that there is some anchoring effect (even if it is "low") at an average pore size below 0.5μm. Note that a concentration less than 1% is needed to produce surface features with an average size between 0.3 and 0.5μm. One of ordinary skill in the art would have been motivated at the time of invention to use a concentration less than 1% to determine the point at which adhesion is improved over the adhesion produced without treatment.

Applicant has previously argued that U.S. Patent 5,039,546 to Chung *"is thus intended for a purpose completely different from the purpose according to the present invention."* Applicant has also argued that *"according to Chung et al. the fluoride ion containing solution should have a pH value greater than 3...This differs from the teachings of the present invention, according to which the pH of the hydrofluoric acid solution...should be in the range of 1.6 to 3.0."*

The arguments are not persuasive because the purpose of the treatment is irrelevant to the claimed invention and the pH is similarly not part of the claimed invention. Chung clearly reads on the invention as broadly claimed by applicant.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 34, 37 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34 and 37 recite the limitation "said metallic oxide". There is insufficient antecedent basis for this limitation in the claims.

Claim 51 recites the limitation "said treatment with the aqueous solution containing fluoride ions". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,039,546 to Chung et al.

Chung teaches a process of treating a metallic bone implant consisting essentially of treating the metallic bone implant with an aqueous solution containing fluoride ions in a concentration greater than 0% and up to 3% (Col. 3,Lines 27-29) where the aqueous solution is free from sodium and sodium ions, and being a solution of a fluoride selected from the group

consisting of lithium fluoride, cesium fluoride, potassium fluoride, ammonium fluoride, stannous fluoride, or any combination thereof. (Col. 2, Lines 56-63)

Regarding Claim 23, Chung teaches that the surface of the metallic bone implant after the treatment with the aqueous solution containing fluoride ions has essentially the same morphology as the surface of the implant before said treatment. (Col. 4, Lines 14-26)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20, 30, 37, and 79-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP-3146679 to Haruyuki.

Haruyuki teaches a method for treating the surface of a titanium biorepair implant and increasing the strength of the bond between bone tissue and the metallic implant. Haruyuki describes treatment of the titanium implant in a 1-6% solution of hydrofluoric acid for a time of 30 seconds to 3 minutes. It is assumed that that the hydrofluoric acid solution is free of sodium ions.

Although Haruyuki stresses the use of a post treatment with hydrogen peroxide, the use of hydrofluoric acid alone is clearly contemplated in Comparative Example 2. The results described in Table No.1 indicate that post treatment is not needed to affect the surface properties. Note the values of Rz are the same for example 2 and comparative example 2. The purpose of the hydrogen peroxide post treatment is to reduce tissue irritation (Page 4 Line 30). Haruyuki teaches that only slight changes in morphology are needed to increase the attachment strength of the implant. Haruyuki indicates that features with an average depth below 0.5 μm would have a small anchoring effect (Page 4 Lines 21-26).

Claims 79-81 differ from Haruyuki only by specifying various concentration ranges for hydrofluoric acid. A person having ordinary skill in the art at the time of the claimed invention would have found it obvious to modify Haruyuki by using different concentrations because same were known to be cause effective variables and routine experimentation would have been expected to optimize them. *In re* Boesch, 205 USPQ 215 (CCPA 1980).

Changes in temperature, concentrations, or other process conditions of an old process, do not impart patentability unless the recited changes are critical, i.e., they produce a new and unexpected result. The results produced by the cited ranges in claims 79-81 do not produce results that are new or unexpected, i.e. improved adhesion to bone tissue.

Furthermore, Haruyuki teaches that indicates that features with an average depth below 0.5 μm would have a small anchoring effect (Page 4 Lines 21-26). This statement suggests that there is some improvement in implant-adhesion at HF concentrations below 1%. Note that a concentration less than 1% is needed to produce surface features with an average size between 0.3 and 0.5μm. Therefore, the skilled artisan would have been motivated to use a concentration less than 1% to determine the point at which cell tissue adhesion is improved over the adhesion occurring without treatment.

Regarding Claim 20, although it is not explicitly stated in Haruyuki, It may be assumed that the surface of the metallic bone implant after the treatment with the aqueous solution containing fluoride ions has essentially the same morphology as the surface of the implant before said treatment since the claimed treatment processes are the same and Haruyuki indicates that

the changes in average feature size are small compared to the untreated implant. Note that the untreated implant has average feature depth of 0.3μm, and treated implants may have an average feature size of 0.5 μm.

Regarding Claims 30 and 37, although it is not explicitly stated, it may be assumed that the surface of the titanium implant is initially covered with a thin layer of titanium oxide because Haruyuki does not use an oxygen-free environment and a thin oxide layer would otherwise be naturally formed on the surface.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,039,546 to Chung et al. in view of the admitted prior art.

As applied above, Chung teaches the method of the invention substantially as claimed, but does not teach post treatment with a solution containing calcium ions. The admitted prior art (Page 7 Lines 10-15) describes post treatment of an implant with a solution of calcium ions in order to determine the biocompatibility of the treated implant.

It would have been obvious to one of ordinary skill in the art at the time of invention to treat the implant with a solution containing calcium ions, in order to determine biocompatibility of the implant.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP-3146679 to Haruyuki in view of the admitted prior art.

As applied above, Haruyuki discloses the method of the invention substantially as claimed, but does not teach post treatment with a solution containing calcium ions. The admitted prior art (Page 7 Lines 10-15) describes post treatment with a solution of calcium ions.

It would have been obvious to one of ordinary skill in the art at the time of invention to treat the implant with a solution containing calcium ions, in order to determine biocompatibility of the implant.

Allowable Subject Matter

Claims 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 34 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roberts Culbert whose telephone number is (571) 272-1433. The examiner can normally be reached on Monday-Friday (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Mills can be reached on (571) 272-1439. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R. Culbert

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